

Substitute for form 1449A/PTO		Complete If Known			
		Application Number		10/076,691	
		Filing Date		February 14, 2002	
		First Named Inventor		Shepard, Michael H	
		Art Unit		1632	
		Examiner Name		Dave Nguyen	
		Attorney Docket Number		016930-000630US	
Sheet	1	of	2		

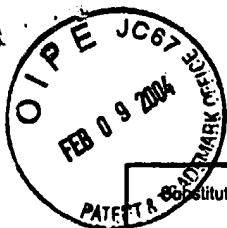
U.S. PATENT DOCUMENTS+						
Examiner Initials*	Cite No. ¹	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
D	1.	6,348,352 B1	02-19-2002	Shepard et al.	Bu	
D	2.	USSN 07/948,289	N/A (Filed 09-18-1992)	Shepard et al.	L	
D	3.	USSN 08/379,168	N/A (Filed 01-27-1995)	Shepard et al.		

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				
D	4.	WO	94/06910 A1	03-31-1994	Canji, Inc.	—	<input type="checkbox"/>
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Sheet 2 of 2

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
DAW	5.	KOLATA, G., "In the rush toward gene therapy, some see a high risk of failure," <u>The New York Times</u> ; page C3, Tuesday, July 25, 1995.	
	6.	LIM, B. et al., "Long-term expression of human adenosine deaminase in mice transplanted with retrovirus-infected hematopoietic stem cells" <u>Proc.Natl.Acad.Sci.U.S.A.</u> 88:8892-8896 (1991).	
	7.	ORKIN, S. et al., "Report and recommendations of the panel to assess the NIH investment in research on gene therapy" December 7, 1995.	

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<i>Complete If Known</i>	
Application Number	08/403,797
Filing Date	December 4, 1995
First Named Inventor	Shepard, H. Michael
Group Art Unit	1633
Examiner Name	Dave Nguyen
Attorney Docket Number	016930-000600US

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First Named Inventor	Shepard, H. Michael
Group Art Unit	1633
Examiner Name	Dave Nguyen

Attorney Docket Number 016930-000600US

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

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(D)	11	Anderson, "Human Gene Therapy," <i>Science</i> , 258:808-813 (1992)	
	12	Baker et al., "Suppression of Human Colorectal Carcinoma Cell Growth by Wild-Type p53," <i>Science</i> , 249:912-915 (1990)	
	13	Callahan, "p53 Mutations, Another Breast Cancer Prognostic Factor," <i>J. Natl. Canc. Inst.</i> , 84(11):826-827 (1992)	
	14	Casey et al., "Growth suppression of human breast cancer cells by the introduction of a wild-type p53 gene," <i>Oncogene</i> , 6:1791-1797 (1991)	
	15	Chen et al., "Genetic Mechanisms of Tumor Suppression by the Human p53 Gene," <i>Science</i> , 250:1576-1580 (1990)	
	16	Chen et al., "Expression of wild-type p53 in human A673 cells suppresses tumorigenicity but not growth rate," <i>Oncogene</i> , 6:1799-1805 (1991)	
	17	Cheng et al., "Suppression of acute Lymphoblastic Leukemia by the Human Wild-Type p53 Gene," <i>Cancer Research</i> , 52(1):222-226 (1992)	
	18	Correll et al., "Production of human glucocerebrosidase in mice after retroviral gene transfer into multipotential hematopoietic progenitor cells," <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 86:8912-8916 (1989)	
	19	Crystal, R.G., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," <i>Science</i> , 270:404-410 (1995)	
	20	Danos et al., "Safe and efficient generation of recombinant retroviruses with amphotropic and ecotropic host ranges," <i>Proc. Natl. Acad. Sci. (U.S.A.)</i> , 85:8480-8484 (1988)	
	21	Droz et al., "Long-term Survivors after Salvage High Dose Chemotherapy with Bone Marrow Rescue in Refractory Germ Cell Cancer," <i>Eur. J. Cancer</i> , 27(7):831-835 (1991)	
	22	Finlay et al., "The p53 Proto-oncogene can act as a Suppressor of Transformation," <i>Cell</i> , 57:1083-1093 (1989)	
	23	Friedmann, T., <i>Cancer Supp</i> , 70(6):1810-1817 (1991)	
	24	Gaidano et al., "p53 mutations in human lymphoid malignancies Association with Burkitt lymphoma and chronic lymphocytic leukemia," <i>Proc. Natl. Acad. Sci. (U.S.A.)</i> , 88:5413-5417 (1991)	
	25	Gerwin et al., "Mutant p53 can induce tumorigenic conversion of human bronchial epithelial cells and reduce their responsiveness to a negative growth factor, transforming growth factor β_1 ," <i>Proc. Natl. Acad. Sci. (U.S.A.)</i> , 89:2759-2763 (1992)	

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Application Number	08/403,797
Filing Date	December 4, 1995
First Named Inventor	Shepard, H. Michael
Group Art Unit	1633
Examiner Name	Dave Nguyen

Attorney Docket Number

016930-000600US

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
DR	26	Guild et al., "Retroviral transfer of a murine cDNA for multidrug resistance confers pleiotropic drug resistance to cells without prior drug selection," <i>Proc. Natl. Acad. Sci. (USA)</i> , 85:1595-1599 (1988)	
	27	Gutierrez et al., "Gene therapy for Cancer," <i>The Lancet</i> , 339:715-721 (1992)	
	28	Isaacs et al., "Wild-Type p53 Suppresses Growth of Human Prostate Cancer Cells Containing Mutant p53 Alleles," <i>Cancer Research</i> , 51:4716-4720 (1991)	
	29	Isola et al., "Association of Overexpression of Tumor Suppressor Protein p53 with Rapid Cell Proliferation and Poor Prognosis in Node-Negative Breast Cancer Patients," <i>J. Natl. Canc. Inst.</i> , 84(14):1109-1114 (1992)	
	30	Johnson et al., "Expression of Wild-Type p53 is not Compatible with Continued Growth of p53-Negative Tumor Cells," <i>Molecular and Cellular Biology</i> , 11(1):1-11 (1991)	
	31	Lavigne et al., "High Incidence of Lung, Bone, and Lymphoid Tumors in Transgenic Mice Overexpressing Mutant Alleles of the p53 Oncogene," <i>Molecular and Cell Biology</i> , 9(9):3982-3991 (1989)	
	32	Ledley et al., "Clinical Considerations in the Design of Protocols for Somatic Gene Therapy," <i>Human Gene Therapy</i> , 2:77-83 (1991)	
	33	Lee, "Tumor suppressor genes: a new era for molecular genetic studies of cancer," <i>Breast Cancer Research and Treatment</i> , 19:3-13 (1991)	
	34	Levine et al., "The p53 tumour suppressor gene," <i>Nature</i> , 351:453-456 (1991)	
	35	Malkin et al., "Germ Line p53 Mutations in a Familial Syndrome of Breast Cancer, Sarcomas, and Other Neoplasms," <i>Science</i> , 250:1233-1238 (1990)	
	36	Miller et al., "Gene Transfer by Retrovirus Vectors Occurs Only in Cells That Are Actively Replicating at the Time of Infection," <i>Molecular and Cellular Biology</i> , 10 (8):4239-4242(1990)	
	37	Miller et al., "p53 Mutations in Human Lung Tumors," <i>Cancer Research</i> , 52:1695-1698 (1992)	
	38	Nigro et al., "Mutations in the p53 gene occur in diverse human tumour types," <i>Nature</i> , 342:705-708 (1989)	
	39	Rill et al., "An Approach for the Analysis of Relapse and marrow Reconstitution After Autologous Marrow Transplantation Using Retrovirus-Mediated Gene Transfer," <i>Blood</i> , 78(10):2694-2700 (1992)	
	40	Rotter et al., "p53 and Human malignancies," <i>Advances in Cancer Research</i> , 57:257-272 (1991)	

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
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(D)	41	Shaw et al., "Induction of apoptosis by wild-type p53 in a human colon tumor-derived cell line," <i>Proc. Natl. Acad. Sci. (U.S.A.)</i> , 89:4495-4499 (1992)
	42	Sikora, K., "Gene therapy for cancer," <i>TIBTECH</i> , 11:197-201 (1993)
	43	Srivastava et al., "Germ-line transmission of a mutated p53 gene in a cancer-prone family with Li-Fraumeni syndrome," <i>Nature</i> , 348:747-749 (1990)
	44	Takahashi et al., "The retinoblastoma gene functions as a growth and tumor suppressor in human bladder carcinoma cells," <i>Proc Natl. Acad Sci. (U.S.A.)</i> , 88:5257-5261 (1991)
	45	Takahashi et al., "Wild-type but not Mutant p53 Suppresses the Growth of Human Lung Cancer Cells Bearing Multiple Genetic Lesions," <i>Cancer Research</i> , 52:2340-2343 (1992)
	46	Thor et al., "Accumulation of p53 Tumor Suppressor Gene Protein: An Independent marker of Prognosis in Breast Cancers," <i>J. Natl. Canc. Inst.</i> , 84(11):845-855 (1992)
	47	Shaw et al., "Induction of apoptosis by wild-type p53 in a human colon tumor-derived cell line," <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 89(10):4495-4499 (1992)
	48	Yerly-Motta et al., "Comparative preclinical study of three bone marrow purging methods using PCR evaluation of residual t(14;18) lymphoma cells," <i>Leuk. Lymphoma</i> , 23 (3-4):313-321 (1996)
	49	Pei et al., "Preliminary application of a low molecular weight tumor suppressor in purged autologous bone marrow transplantation," <i>The Cancer Journal</i> , Vol. 5 (1992)
	50	Cone et al., <i>PNAS</i> , 81:6349-6353 (1984)
	51	Pei et al., EMBASE database, AN: 92206003, <i>Cancer Journal</i> , 5/3:142-145 (1992)
	52	Chen et al., <i>Oncogene</i> , 6:1799-1805 (1991)
	53	Friedmann, <i>Cancer Supplement</i> , 70,6:1810-1817 (1992)
	54	Huang et al., <i>Science</i> , 242:1563-1566 (1988)
	55	Masdasinghe et al., <i>Seminars in Oncology</i> , 23,1:4-21 (1996)

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DM	56	Culver et al., "Gene therapy for solid tumors," <i>British Medical Bulletin</i> , 51:192-204 (1995)	
DM	57	Carbone et al., "In vivo gene therapy of human lung cancer using wild-type p53 delivered by a retrovirus," <i>J. Natl. Cancer Inst.</i> , 86:1437-1438 (1994)	
DM	58	Huang et al., "Suppression of the neoplastic phenotype by replacement of the RB gene in human cancer cells," <i>Science</i> , 242:1583-1586 (1988)	

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